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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,401	10/16/2001	Jose L. Francese	6530.0145-01	3026

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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	PAPER NUMBER
3735	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/977,401	FRANCESE ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/5/07 has been entered.

Claim Objections

Claim 1 is objected to because of the following informalities:

On line 15 of claim 1, "the opening" should be replaced with "an opening". Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the suction source connected to the suction port, the first medical device, which receives suction and is inserted into the body lumen, connected to the first port, and the second medical device, which receives suction and is inserted into the body lumen, connected to the second port must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Lines 5-6 of claim 1 recite, "the first medical device that receives suction and inserts into a body lumen". Lines 7-8 recite, "second medical device that receives suction and inserts into the body lumen". In both cases,

the body lumen, being part of the human body, is non-statutory subject matter and cannot be positively claimed. For example, amending the limitation of lines 5-6 to read "the first medical device that receives suction and is adapted to be inserted into a body lumen" might overcome this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2 recites that the second medical device is a suction device. However, claim 1, upon which claim 2 depends, recites that the adapter is connected to a suction source at a suction port and accommodates a first medical device a first port and a second medical device at a second port. The instant specification fails to describe an adapter connected or adapted to be connected to two suction devices or a suction device and a suction source at the same time. The instant specification fails to describe the second port accommodating any suction device at all.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, in the preamble of the claim, "A suction adapter for use with first and second medical devices". However, lines 4-5 of claim 1 recite, "a first device port accommodating the first medical device" and lines 6-7 recite, "a second device port accommodating the second medical device". Since the preamble merely states that the adapter is *for use with* the first and second medical devices, but the body of the claim positively recites the first and second medical devices being accommodated in the first and second ports, it is wholly unclear whether the first and second devices are part of the claimed invention. For the purpose of this examination only and based on the applicants' specification, which shows in figures 24-32 and on pp. 25-28 a suction adapter that does not include the two medical devices as part of the invention, the examiner is assuming that the medical devices are not part of the claimed invention and that the first and second ports are merely "for" (capable of) accommodating the first and second medical devices. In any case, the applicants must amend the claim to clarify their intent. If the first and second medical devices are part of the claimed invention, then the preamble should be amended to recite "A system" rather than " A suction adapter for use with first and second medical devices capable of accommodating suction", and the body of the claim should also be amended accordingly (for example, the system should comprise an assembly having a manifold and first and second

medical devices, rather than merely a manifold). If the first and second medical devices are not part of the claimed invention, then the recited language on lines 4-5 of claim 1 should be replaced with "a first device port for accommodating the first medical device" and the recited language on lines 6-7 of the claim should be replaced with "a second device port for accommodating the second medical device".

Claim 1 additionally claims "a suction adapter" in the preamble of the claim but recites, "a suction port connected to a suction source" in the body of the claim. Furthermore, the body of the claim merely claims " a manifold" on line 2, but states that the suction port of the manifold is "connected to a suction source". It is therefore unclear whether the claimed invention is limited to the adapter itself, as recited in the preamble and implied by the recitation of merely "a manifold", or the adapter in conjunction with the suction source, as recited in the body of the claim and implied by the recited connection with the suction source. For the purpose of this examination only and based on the applicants' specification, which shows in figures 24-32 and on pp. 25-28 a suction adapter that does not include the suction source, the examiner is assuming that the suction source is not part of the claimed invention and that the suction port is merely "for" or configured to connect with the suction source. In any case, the applicants must amend the claim to clarify their intent. If the suction source is part of the claimed invention, then the applicants should replace "a suction adapter" with " A system" and the body of the claim should be amended accordingly (for example, the system should comprise and assembly including a manifold and a suction source, rather than just a manifold). If the suction source is not intended to be part of the claimed

invention, then "a suction port connected to a suction source" on lines 4-5 of claim 1 should be replaced with "a suction port for connection to a suction source".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> Or
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The present application attempts to claim the benefit of the earlier filing date of US Patent Application Serial No. 09/079,168 and 08/756,260. However, the claimed suction adapter of the present application is not fully supported by the disclosure of the parent applications. Therefore, for the purpose of examination, the earliest effective filing date of the claimed subject matter of the present application is October 16, 2001, which is the filing date of the present application.

Claims 1-3, 12-15, 17, 19, and 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Us Patent No. 6,142,980 to Schalk. Schalk teaches an adapter

comprising a manifold having at least three ports, the ports including a suction port 24 for connection to a suction source 22, 28 (see entire document, especially figs. 1-3; col. 2, lines 29-67 of Schalk), wherein Schalk discloses the roller type of positive displacement aspiration pump as creating a vacuum in the suction tube, thereby acting as a suction source. A first device port 20 is for or capable of accommodating a first medical device 12 that receives suction and is capable of being inserted into a body lumen. A second device port 66 is also capable of accommodating a second medical device that receives suction and is capable of insertion into a body lumen. A flexible flow valve 50 is positioned in a first flow path between the first port and the second port and in a second flow path between the first port and the suction port. The valve permits simultaneous fluid flow between the suction port and both the first and second device ports, wherein the fluid flow between the suction port and the first device port is through an opening that is configured to increase due to fluid flow from the first port to the suction port (see entire document, especially figs. 1-3; col. 3, line 7-col. 4, line 33 of Schalk).

The applicants should refer to the rejection under 112, 2nd paragraph for the examiner's treatment of the claims in view of the discrepancy between the preamble and the body of the claim 1.

Regarding claim 2, the first medical device is capable of accommodating an endoscope and the second port is capable of accommodating a suction device.

Regarding claim 3, the valve includes a membrane 56 (see entire document, especially figs. 3, 4; col. 3, lines 10-26 of Schalk).

Regarding claim 12, the opening of the flexible flow valve is substantially centrally located (see entire document, especially figs. 3 & 4 of Schalk).

Regarding claim 13, the flexible flow valve is substantially flat (see entire document, especially figs. 3 & 4 of Schalk).

Regarding claim 14, the flexible flow valve is conical (see entire document, especially figs. 3 & 4 of Schalk).

Regarding claim 15, the flexible flow valve is dome-shaped (see entire document, especially figs. 3 & 4 of Schalk).

Regarding claims 17-20, the applicants should note that the language describing the manufacture of the valve is merely "product-by-process" language, wherein the patentability of such a limitation depends on the structure implied by such process rather than the process itself. See MPEP § 2113. Schalk teaches a manifold and valve as implied by the language of claim 17, and a first component including a first port and second component including a second port, as implied by the language of claim 19. With further regard to claim 20, the second component is a tee-connector (see entire document, especially figs. 1-4 of Schalk).

Regarding claims 21 and 22, the manifold has a third device port 64 configured for accommodating a third medical device (see entire document, especially figs. 3 & 4 of Schalk). With further regard to claim 22, a second flexible flow valve 80 has an opening, wherein the second valve is located between the third device port and both the second device port and the suction port (see entire document, especially figs. 3 & 4 of

Schalk). While Schalk does not address the materials used to make the second valve, any material is flexible, or capable of being bent or flexed.

Regarding claim 23, the opening is configured to increase due to a difference in pressure at proximal and distal sides of the valve (see entire document, especially figs. 3, 4; col. 3, lines 7-40 of Schalk).

Regarding claim 24, the opening is configured to increase due to an application of suction (see entire document, especially figs. 3 & 4; col. 3, lines 6-40 of Schalk).

Claims 1-3, 12-15, 17-20, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,346,477 to Edwards et al. Edwards teaches an adapter capable of being used with first and second medical devices comprising a manifold 40 having at least three ports 82, 84, 88, including a suction port 84 capable of connection to a suction source, a first device port 82 for or capable of accommodating a first medical device that receives suction, and a second device port 88 for or capable of accommodating a second medical device that receives suction (see entire document, especially fig. 8 of Edwards). A flexible flow valve 86 is positioned in both a first flow path between the first device port and the second device port and a second flow path between the first device port and the suction port. The valve appears to permit simultaneous flow between the suction port and both the first and second device ports, wherein the fluid flow path between the suction port and the first device port 82 is through an opening, wherein the opening is configured to increase due to fluid flow (see entire document, especially fig. 8; col. 7, line 20-32 of Edwards).

The applicants should refer to the rejection under 112, 2nd paragraph for the examiner's treatment of the claims in view of the discrepancy between the preamble and the body of the claim 1.

Regarding claim 2, the first medical device may be an endoscope and the second may be a suction device.

Regarding claim 3, the valve includes a membrane (see entire document, especially fig. 8; col. 7, lines 20-32 of Edwards).

Regarding claims 12-15, the opening of the flexible flow valve is centrally located, wherein the valve is substantially flat, conical, and dome-shaped (see entire document, especially fig. 8 of Edwards).

Regarding claims 17-20, the applicants should note that the language describing the manufacture of the valve is merely "product-by-process" language, wherein the patentability of such a limitation depends on the structure implied by such process rather than the process itself. See MPEP § 2113. Schalk teaches a manifold and valve as implied by the language of claim 17, and a first component including a first port and second component including a second port, as implied by the language of claim 19. With further regard to claim 20, the second component is a tee-connector (see entire document, especially figs. 1-4 of Schalk).

Regarding claim 23, the opening of a duckbill valve is configured to increase due to a difference in pressure at proximal and distal sides of the valve or due to an application of suction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al., as applied to claims above. Edwards teaches a flexible flow valve 89 in the form of a duckbill type valve, wherein other types of valves may be used in its place (see entire document, especially col. 7, lines 20-32 of Edwards). Edwards does not expressly state that the valve membrane has three flaps, that the vale has a plurality of first flaps having a first shape that alternate with a plurality of second flaps having a second shape different form the first shape, or that the valve is multi-prism shaped. However, the applicant has not disclosed that using a flow valve configured in any of these ways solves any stated problem or is for any particular purpose. Moreover, it appears that the flow valve of Edwards et al., or the applicants' invention, would perform equally well with any type of flexible flow valve configuration. Accordingly the use of a valve having three flaps, a valve having a plurality of first flaps with a first shape that alternates with a plurality of second flaps having a second shape differing from the first shape, or a valve having a multi-prism, is deemed a mere design consideration which fails to patentably distinguish over the prior art of Edwards.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schalk, as applied to claims above, and further in view of US Patent No. 4,898,669 to Tesio. Schalk discloses the membrane as being made of a plastic (see entire document, especially col. 3, lines 13-18 of Schalk), wherein clearly the plastic must be biocompatible in order to allow for the device as described to function properly. Schalk is silent as to the material used for the manifold. However, Tesio teaches a device through which blood flows, wherein the device is made of a biocompatible plastic (col. 3, lines 6-22 of Tesio). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the biocompatible plastic material of Tesio as the material for the manifold of Schalk, since Schalk teaches a device through which blood flows and Tesio discloses biocompatible plastic as an appropriate material for such a device.

Response to Arguments

Applicant's arguments filed 2/5/07 have been fully considered but they are not persuasive.

The applicants argue that neither Schalk nor Edwards discloses or suggests the invention as claimed in independent claim 1. Specifically, the applicants state the cited reference must actually perform the intended use, with reference to the ports, based on amendments to the claim. However, as explained in the rejection set forth above under 35 U.S.C. 112, 2nd paragraph, there is a discrepancy between portions of independent claim 1 as to whether the first medical device, second medical device, and suction

source are part of the claimed invention. The preamble of the claim merely recites "A suction adapter for use with first and second medical devices". Such an adapter is not inclusive of any of a suction device, first medical device, or second medical device. Further, the body of the claim states that the adapter merely comprises a manifold and a flexible flow valve, implying that none of the suction source or first or second medical device form part of the claimed adapter. In contrast, lines 3-8 claim "a suction port connected to a suction source, a first device port accommodating the first medical device that receives suction and inserts in to a body lumen for performing a first procedure, and a second device port accommodating the second medical device that receives suction and inserts into the body lumen for performing a second procedure". Because of the discrepancy in language, it is unclear whether the invention is actually a system comprising a flexible flow valve and an assembly which includes a manifold, a suction source connected to a suction port of the manifold, a first medical device connected to a first port of the manifold, and a second medical device connected to a second port of the manifold, or if the invention is merely the adapter itself. Since the applicants' specification describes the adapter alone and merely as being capable of use with a suction source and first and second medical devices and further fails to show or describe an embodiment of a system comprising the manifold with the suction source and first and second medical devices, it is reasonable to assume that the claimed invention does not include the suction source and first and second medical devices. Using such an assumption, the ports of the adapter must merely be capable of coupling with any of the suction source, first medical device, and second medical device.

Therefore, both Edwards and Schalk indeed meet all of the limitations set forth by the claim, in light of the problem under 35 U.S.C. 112, 2nd paragraph, as described in the rejections set forth above under 35 U.S.C. 102(b) and 102(e).

With regard to the applicants' argument that the port 64 of Schalk is incapable of accommodating a medical device that receives suction and inserts into the body lumen for performing a procedure, the applicants' arguments are moot, since port 66 has been identified as the second device port. However, the applicants' arguments indicate that the applicants believe that the "accommodation" requires forming a fluid pathway between the port and the medical device. The claim language does not require that the port form a fluid pathway between from the port to within the second device. The language merely requires that the port be capable of accommodating such a medical device. The port 66 of Schalk is clearly capable of such accommodation, wherein such accommodation may be made without removal of the poppet valve 74 or any feature of the adapter.

The applicants further argue that the valve of Schalk does not disclose or suggest a flexible flow valve having an opening positioned in a first flow path between the first device port and the second device port and a second flow path between the first device port and the suction port. However, the valve 50 appears to allow fluid to flow from first port 20 to suction port 24 and further appears to allow fluid to flow from first port 20 to second port 66. The applicants point out the operation of duckbill valve 50 and poppet valve but fails to make a cohesive argument as to how the operation of

these valves show that the valve 50 does not allow the first and second fluid flow pathway as described.

As to the Edwards reference, the applicants also contend that Edwards does not teach that the port 88 accommodates a medical device that receives suction and inserts into the body lumen for performing a procedure. The applicants should refer to the rejections under 35 U.S.C. 101 and 35 U.S.C. 112, 2nd paragraph for the treatment of this language due to the discrepancy in claim language in claim 1. Again, the applicants statements here indicate that the applicants believe the "accommodation" as claimed requires a fluid pathway between the port and the interior of the medical device. However, the current claim language indicates no such requirement. The accommodation may be made with such a fluid pathway and such that no component of the adapter of Edwards requires removal.

Therefore, the rejection of claims as set forth above stand.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

pcm

Robert S Nasser
Robert Nasser
Primary Examiner